In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: January 24, 2025

LINDY SELLS,	*	PUBLISHED
Petitioner,	*	No. 20-745V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Measles-Mumps-Rubella ("MMR") Vaccine; Varicella Vaccine; Acute Disseminated Encephalomyelitis ("ADEM").
Respondent.	*	

Renee J. Gentry, The Law Office of Renee J. Gentry, Washington, DC, for Petitioner.
Emilie Williams, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On June 22, 2020, Lindy Sells ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018),[2] alleging that she suffered acute disseminated encephalomyelitis ("ADEM") as a result of receiving a measles-mumps-rubella ("MMR") vaccine and/or a varicella vaccine on October 1, 2018. Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating "this case is not appropriate for compensation under the terms of the Vaccine Act." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 23).

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018) ("Vaccine Act" or "the Act"). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards,[3] the undersigned finds Petitioner has provided preponderant evidence that the MMR and/or varicella vaccines Petitioner received on October 1, 2018 caused her to develop ADEM, satisfying Petitioner's burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is entitled to compensation.

I. ISSUES TO BE DECIDED

The parties dispute diagnosis and the Althen prongs. Joint Prehearing Submission ("Joint Submission"), filed Mar. 26, 2024, at 1 (ECF No. 105). Regarding diagnosis, Petitioner contends she suffers from ADEM. Id. Respondent asserts that Petitioner has failed to show preponderant evidence of ADEM and that her symptoms are "consistent with other conditions, including liver disease and thyroid disease." Respondent's Pre-hearing Submission ("Resp. Br."), filed Apr. 11, 2024, at 1-2, 14 (ECF No. 111); see also Joint Submission at 1.

As to causation, the parties dispute both whether there is sufficient evidence to conclude that MMR and/or varicella vaccines can cause ADEM and whether Petitioner's alleged ADEM was caused by her MMR and/or varicella vaccines. Joint Submission at 2.

II. BACKGROUND

A. Procedural History

Petitioner filed her petition on June 22, 2020, followed by medical records and an affidavit on June 25, 2020. Petition; Petitioner's Exhibits ("Pet. Exs.") 1-15. The case was subsequently reassigned to the undersigned. Notice of Reassignment dated July 10, 2020 (ECF No. 12). Petitioner filed additional medical records on November 5, 2020. Pet. Ex. 16. Respondent filed his Rule 4(c) report on December 17, 2020, arguing against compensation. Resp. Rept. at 2.

On March 8, 2021, Petitioner filed an expert report from Dr. Carlo Tornatore. Pet. Ex. 17. On July 6, 2021, Respondent filed an expert report from Dr. Thomas Leist. Resp. Ex. A.

The undersigned held a Rule 5 conference on September 28, 2021. Rule 5 Order dated Sept. 29, 2021 (ECF No. 37). The undersigned preliminarily found Petitioner would be able to

[3] While the undersigned has reviewed all of the information filed in this case, only those filings and records that are most relevant will be discussed. See Moriarty v. Sec'y of Health & Hum. Servs., 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision."); see also Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

satisfy all three Althen prongs. Id. at 1. Further, the undersigned preliminarily found that Petitioner's alcoholism and cirrhosis presented later in time than her ADEM and that there is no evidence that ADEM was caused by her cirrhosis. Id. at 2. The parties agreed to begin settlement negotiations. Id.

Between October 2021 and July 2022, Petitioner continued to file medical records and supporting documentation. Pet. Exs. 27-42. On July 7, 2022, Respondent requested that the case proceed on a litigation track. See Order dated July 7, 2022 (ECF No. 69). The parties subsequently requested an entitlement hearing, and one was set for May 2024. Joint Status Report, filed Aug. 22, 2022 (ECF No. 71); Prehearing Order dated Nov. 29, 2022, at 1 (ECF No. 78)

On July 22, 2022, Respondent filed a supplemental report from Dr. Leist. Resp. Ex. I. Petitioner filed a supplemental report from Dr. Tornatore on October 6, 2022. Pet. Ex. 43. Between December 2022 and April 2024, Petitioner continued to file updated medical records and supporting documentation. Pet. Exs. 44-56.

An entitlement hearing was held on May 1, 2025. Transcript ("Tr.") 1. Petitioner, Dr. Tornatore, and Dr. Leist testified at the hearing. Tr. 3. Following the hearing, Petitioner submitted an article referenced by Dr. Tornatore during his testimony and Respondent refiled an exhibit that was missing two pages. Pet. Ex. 57; Resp. Ex. G. The parties agreed not to submit post-hearing briefs. Joint Status Report, filed June 10, 2024 (ECF No. 120).

This matter is now ripe for adjudication.

B. Medical Terminology

1. Acute Disseminated Encephalomyelitis

Acute disseminated encephalomyelitis ("ADEM") is "an immune-mediated disorder of the central nervous system (CNS)" which usually begins with an "abrupt onset of neurologic symptoms and signs within days to weeks after a viral infection or immunization." Pet. Ex. 20 at 1.[4] ADEM is usually triggered by an inflammatory response to viral infections and vaccinations. Id. at 3.

While the International Pediatric Multiple Sclerosis Study Group ("IPMSSG") has proposed a consensus definition of ADEM for children, there are no specific diagnostic criteria

[4] Farshid Noorbakhsh et al., Acute Disseminated Encephalomyelitis: Clinical and Pathogenesis Features, 26 Neurologic Clinics 759 (2008).

for diagnosis in adults. Pet. Ex. 55 at 2;[5] see also Resp. Ex. J at 6 ("There are no international definitions of ADEM in adults.").[6]

The National Organization for Rare Diseases ("NORD") notes that ADEM symptoms vary depending on factors such as the location of brain lesions and the age of onset. Pet. Ex. 43 at 4. Additionally, individuals may develop "a mild, limited form of the disorder." Id. Involvement of the peripheral nervous system is "rare" in children with the illness and "more common in adult patients." Pet. Ex. 20 at 3.

C. Summary of Medical Records[7]

Petitioner received MMR and varicella vaccines at a Walgreens Pharmacy on October 1, 2018. Pet. Ex. 1 at 2; Pet. Ex. 2 at 2. Prior to her receipt of these vaccinations, Petitioner's past medical history was significant for hypertension, depression, anxiety, appendectomy, and C-section. Pet. Ex. 10 at 7; Pet. Ex. 8 at 7; Pet. Ex. 6 at 8.

On October 6, 2018, Petitioner had a purified protein derivative ("PPD") tuberculosis skin test placed on her right forearm. Pet. Ex. 4 at 11. "No chief complaint on file" was noted and no physical examination or review of systems was recorded. Id. Two days later, on October 8, 2018, the PPD test was read as negative. Id. at 19.

On January 7, 2019, Petitioner presented to rheumatologist Louis Perdue, M.D., with a chief complaint of joint pain. Pet. Ex. 10 at 7-9. She was "upset today" and reported "feeling poorly for the last few months." Id. at 7. Petitioner stated she had back spasms at night and pins and needles sensation in her truck as well as stiffness, swelling, and fatigue. Id. She had numbness and pain in her extremities, particularly her legs. Id. She had lost 20 pounds in two months without effort, had difficulty sleeping, and had severe fatigue. Id. Petitioner noted that she had a history of anxiety and was stressed from changing jobs. Id. She reported consuming two to three drinks one time per week. Id. at 7, 16. Physical examination noted tenderness in the knees and metatarsophalangeal joints. Id. at 8. Dr. Perdue's assessment was paresthesia, joint pain, fatigue, and anxiety. Id. He ordered laboratory tests and planned to refer Petitioner to

[5] Kunyi Li et al., Clinical Presentation and Outcomes of Acute Disseminated Encephalomyelitis in Adults Worldwide: Systematic Review and Meta-Analysis, 23 Frontiers Immunology 870867 (2022).

[6] Renata Barbosa Paolilo et al., Acute Disseminated Encephalomyelitis: Current Perspectives, 7 Children 210 (2020).

[7] This summary of medical records is taken in part from the parties' pre-hearing briefs, as the undersigned finds they provided an accurate representation of the records. See Petitioner's Prehearing Memorandum ("Pet. Br."), filed Mar. 6, 2024, at 2-17 (ECF No. 99); Resp. Br. at 2-9.

neurology depending on her test results. Id. Petitioner was prescribed prednisone,[8] gabapentin,[9] and Effexor[10] and instructed to follow-up in four weeks. Id.

Laboratory tests reported on January 13, 2019, had notable results. Pet. Ex. 10 at 10-11. Petitioner had anemia with hemoglobin of 8.9 g/dL (normal range is 11.3 to 14.9). Id. She had elevated inflammatory markers including an erythrocyte sedimentation rate ("ESR")[11] at 116 mm/h (normal range is 0 to 30) and a globulin level of 4.4 g/dL (normal range is 1.8 to 4.0). Id. She had elevated liver enzymes with alkaline phosphate[12] at 123 U/L (normal range is 34 to 104), aspartate aminotransferase ("AST")[13] at 110 U/L (normal range is 11 to 39), and total bilirubin[14] of 1.3 mg/dL (normal range is 0.2 to 1.0). Id. Petitioner's results also showed

[8] Prednisone is "a synthetic glucocorticoid" used as "an anti-inflammatory and immunosuppressant in a wide variety of disorders." Prednisone, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=40742 (last visited Jan. 16, 2025).

[9] Gabapentin is anticonvulsant used in the treatment of partial seizures and neuropathy. Gabapentin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=19523 (last visited Jan. 16, 2025).

[10] Effexor is the trademark name of venlafaxine hydrochloride, an antidepressant and antianxiety agent. Venlafaxine Hydrochloride, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=52779 (last visited Jan. 16, 2025).

[11] Erythrocyte sedimentation rate, or ESR, is "the rate at which erythrocytes precipitate out from a well-mixed specimen of venous blood . . . . [ESR] is increased . . . due to inflammatory disease, hyperfibrinogenemia, active inflammatory disease, and anemia." Erythrocyte Sedimentation Rate, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=102146 (last visited Jan. 16, 2025).

[12] Alkaline phosphate levels are used to detect diseases of the liver and bones. Alkaline Phosphate, Mosby's at 43.

[13] Aspartate aminotransferase, or AST, levels are used "in the evaluation of patients with suspected hepatocellular disease" with increased levels of AST indicating liver diseases, skeletal muscle diseases, and other diseases including hemolytic anemia. Aspartate Aminotransferase, Mosby's at 107-09.

[14] Bilirubin levels are used to evaluate liver function. Bilirubin, Mosby's at 110.

hypothyroidism[15] with an elevated thyroid-stimulating hormone ("TSH")[16] of 9.261 uIU/mL (normal range is 0.340 to 4.410). Id. Petitioner had normal levels of autoimmune antibodies SS-A and SS-B immunoglobin G ("IgG") as well as normal antinuclear antibody ("ANA"), double stranded deoxyribonucleic acid ("dsDNA") antibodies, rheumatoid factor, and Smith IgG. Id. at 10-11.

On April 3, 2019, Petitioner saw endocrinologist Escipion Pedroza, M.D., Ph.D., with complaints of fatigue, weight loss, hair loss, constipation, diarrhea, and elevated TSH due to suspected Hashimoto's thyroiditis.[17] Pet. Ex. 8 at 6. Petitioner reported chronic fatigue for the past four to six months, pain in her feet and legs, neuropathy pain "everywhere," and "foggy brain." Id. Social history noted occasional alcohol use. Id. at 8. The review of systems noted weakness, muscle weakness, and "neuropathy improving symptoms after vaccinations." Id. The neurological examination noted "[alert and oriented] x3. No focal deficits. Gait within normal limits." Id. Dr. Pedroza's assessment was hypothyroidism, disorder of pituitary gland, and "other primary ovarian failure." Id.

Petitioner saw neurologist Rajiv Khurana, M.D., on April 11, 2019, with a chief complaint of weakness and burning in her legs. Pet. Ex. 6 at 16. Petitioner reported neurological symptoms "starting in November 2018." Id. She reported ascending weakness and numbness in her feet which progressed to her legs and trunk as well as weakness in her arms. Id. Petitioner also reported transient periods of double vision. Id. Petitioner explained that she had a progression of symptoms for a few weeks and reported that her symptoms peaked at three weeks. Id. Since then, symptom progression stopped, and she felt a slow improvement. Id. However, she still had "weakness in legs and [felt] tingling, burning[,] and excessive sensitivity in [her] feet." Id. Additionally, she had fatigue, dizziness, pain in her neck and back, trouble sleeping, and poor appetite. Id. at 8-9. She was able to walk unassisted but needed help with stairs or "getting out of [a] couch." Id. at 8. Petitioner recalled having a brief respiratory infection in August or September of 2018 and reported receiving tetanus-diphtheria-acellular pertussis ("Tdap")[18] and MMR vaccines in October 2018. Id. Petitioner had been prescribed gabapentin

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[15] Hypothyroidism is "deficiency of thyroid activity, characterized by decrease in basal metabolic rate, fatigue, and lethargy." Hypothyroidism, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=24430 (last visited Jan. 16, 2025).

[16] Thyroid-stimulating hormone, or TSH, test is used to diagnose primary hypothyroidism with increased levels of TSH indicating primary hypothyroidism and thyroiditis. Thyroid-Stimulating Hormone, Mosby's at 434-36.

[17] Hashimoto's thyroiditis is "a progressive type of autoimmune thyroiditis with lymphocytic infiltration of the gland and circulating antithyroid antibodies; patients have goiter and gradually develop hypothyroidism." Hashimoto's Disease, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=113684 (last visited Jan. 14, 2025).

[18] Petitioner was administered the varicella and MMR vaccines in October 2018. Pet. Ex. 1 at 2; Pet. Ex. 2 at 2. Respondent acknowledged that references to Tdap or other vaccines made at this, and other medical encounters appear to be erroneous. Resp. Br. at 3 n.2.

but was not taking the prescribed dose due to side effects. Id. Her social history noted alcohol use. Id.

Dr. Khurana's neurological examination revealed weakness in both arms (proximal graded -4/5 and distal graded 4+/5) and legs (graded 3-4/5). Pet. Ex. 6 at 10. Petitioner also had dysesthesia in her feet, absent deep tendon reflexes ("DTRs") in her upper and lower extremities, and an unsteady gait, although she walked without a cane. Id. Dr. Khurana noted Petitioner's "cognitive evaluations reveal[ed] no significant impairment in attention, recall, and executive functions." Id. Assessment was "[a]cute onset progressive motor weakness and some sensory symptoms in legs" and Dr. Khurana made a differential diagnosis of acute demyelinating polyradiculoneuropathy, Guillain-Barré Syndrome ("GBS"), spinal cord lesions, and multiple sclerosis ("MS"). Id. Dr. Khurana ordered a lumbar puncture, imaging studies, an electromyography ("EMG")/nerve conduction study ("NCS"),[19] and further laboratory studies. Id. at 20. Dr. Khurana also referred Petitioner to physical therapy. Pet. Ex. 9 at 27.

A lumbar puncture and cerebrospinal fluid ("CSF") analysis[20] were performed on April 16, 2019. Pet. Ex. 6 at 5, 28-29, 35. Petitioner had normal CSF IgG, IgG index, and normal IgG synthesis rate. Id. at 5. Her peripheral IgG level was elevated at 1870 mg/dL (normal range is 694 to 1618). Id. Petitioner had normal CSF glucose and normal CFS protein and no red or white blood cells were seen in the CSF. Id. at 35. Her CSF contained "multiple restriction bands . . . also present in [her] corresponding serum sample." Id. at 5.

An EMG/NCS was performed on April 19, 2019. Pet. Ex. 6 at 25-27. The study showed motor and sensory neuropathic changes in the lower extremities described as mixed denervation changes and bilateral carpal tunnel syndrome.[21] Id. at 27.

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[19] Electromyography is "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation." Electromyography, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15854 (last visited Jan. 16, 2025). Nerve conduction studies are "the measurement of the conduction velocity and latency of peripheral nerves." Nerve Conduction Studies, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=109043 (last visited Jan. 16, 2025).

[20] Lumbar puncture and CSF analysis are used to "assist in the diagnosis of . . . encephalitis, degenerative brain disease, autoimmune disease involving the [CNS], neurosyphilis, and demyelinating disorders (e.g. [MS], acute demyelinating polyneuropathy)." Lumbar Puncture and Cerebral Fluid Examination, Mosby's at 589.

[21] Carpal tunnel syndrome is "an entrapment neuropathy characterized by pain and burning or tingling paresthesias in the fingers and hand, sometimes extending to the elbow. Symptoms result from compression of the median nerve in the carpal tunnel." Carpal Tunnel Syndrome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110370 (last visited Jan. 14, 2025). Petitioner is not alleging that her carpal tunnel syndrome is vaccine related.

Multiple imaging studies were performed on April 25, 2019. A lumbar spine X-ray showed spondylosis with mild anterior listhesis of L4 and L5 and mild facet arthropathy in the lower lumbar segments. Pet. Ex. 11 at 3. Magnetic resonance imagining ("MRI") of the cervical spine showed no evidence of white matter cord lesions. Id. at 4. The cervical spine MRI showed mild disc disease at C5-C6 and C6-C7 and mild cord flattening without cord compression or myelomalacia at C6-C7. Id. at 4-5.

A brain MRI was also performed April 25, 2019. Pet. Ex. 11 at 6-7. The interpreting radiologist, David Silvestri, M.D., stated that it showed "scattered white matter gliotic signal foci throughout the deep, subcortical and periventricular white matter . . . [with the] most confluent and largest on the left [side]." Id. at 6. There were "no infratentorial brain stem or cerebellar lesion[s]." Id. There was no evidence of "active disease." Id. at 7. Dr. Silvestri concluded there was "[e]xtensive widespread white matter gliotic signal change asymmetric and greater on the left involving both subcortical deep and basal ganglia especially the left thalamus." Id. He noted the findings were "worrisome for demyelination disease." Id. at 6-7.

Following this study, Dr. Khurana recommended Petitioner seek further treatment with a "[n]eurologist with expertise in [d]emyelinating disorders as [Petitioner] seems to have disseminated demyelinating lesions in brain." Pet. Ex. 6 at 24.

Petitioner began physical therapy ("PT") on April 22, 2019. Pet. Ex. 9 at 27-28. At the initial PT evaluation, Petitioner reported she was a traveling nurse who received a series of vaccines and began experiencing neurological symptoms in October of 2017.[22] Id. She also complained of progressive weakness, poor balance, and poor stamina. Id. She explained that she was still undergoing diagnostic assessment. Id. On examination, her gait was ataxic,[23] she had diminished reflexes, and she had diminished strength in upper and lower extremities. Id. She had a severe sway when standing with her feet together. Id. at 28. The plan was for twice-weekly PT to improve her strength and balance. Id.

On May 1, 2019, Petitioner presented to neurologist and neuroimmunologist, Jesus Lovera, M.D. Pet. Ex. 7 at 8. Petitioner reported receiving vaccinations October 1, 2018 and "few days later she felt very ill." Id. at 8. She "developed severe pain described as pins-and-needles in her feet as well as low back spasms." Id. The pins and needles sensation and pain in her feet gradually ascended upwards over the next two weeks, as well as weakness in her lower extremities. Id. She reported experiencing double vision for less than a week about one to two weeks after vaccination. Id. at 9. She experienced severe fatigue and cognitive problems with difficulty focusing and processing information. Id. at 8. Her cognitive difficulties led to

[22] Respondent acknowledged that the reference to 2017 is likely to be an error, as the remainder of the records referenced administration of vaccines in 2018. Resp. Br. at 4 n.3.

[23] Ataxic gait is "an unsteady, uncoordinated walk, with a wide base and the feet thrown out, due to some form of ataxia." Ataxic Gait, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=77913 (last visited Jan. 16, 2025).

difficulties at her job and ultimately being fired as a result. Id. Additionally, Petitioner reported that she had congenital problems with her teeth, and dental implants which failed in 2018, resulting in all her teeth being pulled and being replaced by dentures. Id. at 9. In the history of present illness, Dr. Lovera noted that prior to Petitioner's current illness, she had "had no other episodes suggestive of demyelination. In particular [] she denie[d] prior episodes of weakness[,] difficulties walking and vertigo[,] facial pain[,] visual loss[,] or balance problems." Id.

Neurological examination revealed mild cognitive difficulties as well as a tendency to perseverate. Pet. Ex. 7 at 11-12. Petitioner had weakness of the lower extremities bilaterally with the reflexes in the lower extremities diminished relative to the upper extremities. Id. Vibratory sensation was diminished in both the upper and lower extremities but more so in the lower extremities. Id. at 12. Pinprick sensation was diminished in the lower extremities up to two inches below the belly button. Id. Her gait was slow, and she was unable to tandem walk. Id. She had a positive Romberg.[24] Id. Dr. Lovera personally read the April 2019 brain MRI and noted Petitioner had "extensive scattered white matter involvement." Id. He also read the April 2019 cervical spine MRI and noted that he saw no cervical spine lesions. Id. Dr. Lovera concluded that

> [based] on the clinical history, the close relation to the vaccination especially the MMR which is a live [virus] vaccine I think in her case we are dealing with ADEM as opposed to [MS]. The MRI also suggests this [] because of the confluence of the lesions and the involvement of the thalamus. Unfortunately, this MRI was done six months after the onset of symptoms so we do not know if all these lesions occur at the same time as I suspect. Currently there is no evidence of active demyelination in the postcontrast scans. Her spinal tap fits more with what would be expected from ADEM with no oligoclonal bands[25] indicating CNS involvement. The decreased reflexes in the lower extremity makes me suspect that there is also a component of peripheral nerve involvement.

Id. at 13-14. Dr. Lovera's assessment included ADEM, neuropathic pain, hypothyroidism, hypertension, anemia, insomnia, cognitive change, and major depressive disorder. Id. at 13. Dr. Lovera ordered MRIs and psychometric testing and planned to review the EMG/NCS testing. Id. He counseled Petitioner on her disease prognosis and noted it was likely she would continue to have cognitive difficulties and it would be difficult for Petitioner to resume her nursing job. Id. Dr. Lovera recommended Petitioner "apply for the vaccine compensation program . . . [as] there is a clear-cut time relation between the vaccination and the onset of symptoms." Id.

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[24] Romberg sign is "the swaying of the body or falling when standing with the feet close together and the eyes closed." Romberg Sign, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=106448 (last visited Jan. 16, 2025).

[25] Oligoclonal bands are "discrete bands of [IgG] with decreased electrophoretic mobility; their appearance in electrophoretograms of [CSF] when absent in the serum is a sign of possible [MS] or other diseases of the central nervous system." Oligoclonal Bands, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=60106 (last visited Jan. 23, 2025).

Petitioner had a follow-up appointment with Dr. Khurana on June 6, 2019. Pet. Ex. 6 at 12-15. She reported joint, neck, and low back pain, numbness and tingling in her arms and legs, weakness in her legs, dizziness, and sleep problems. Id. at 13. Upon examination, her cognitive function evaluations revealed no significant impairment in attention, recall, or executive function; she had dysesthesia in her feet and sluggish DTRs in all extremities; and her gait was unsteady, but she could walk without a cane. Id. at 14. The assessment included ADEM. Id. The plan was to continue gabapentin for her neurological symptoms and Xanax[26] and Effexor for depression and anxiety. Id. at 15. She was discharged from Dr. Khurana's care to pursue further care through LSU or Ochsner Hospital. Id.

Petitioner continued with PT through November 2019. Pet. Ex. 9 at 6. At her last visit on November 14, 2019, she was noted to be progressing very well; her gait speed and step length was within normal parameters. Pet. Ex. 12 at 32. Short term goals included improving strength, balance, and gait. Id.

On November 18, 2019, Petitioner was admitted to University Medical Center of New Orleans ("University Medical Center") with subacute mental status changes that were attributed to hepatic encephalopathy.[27] Pet. Ex. 14 at 301-03. According to her son, who accompanied her to the emergency department, she had been diagnosed with ADEM and had experienced symptoms of that condition for a year. Id. at 237-38. On admission, she was having difficulty answering some questions, had trouble walking, and was confused. Id. An examination showed Petitioner was lethargic, disoriented and confused with abnormal coordination and gait. Id. at 232. Her cognition and memory were impaired. Id. Head computed tomography "CT" scan done that day revealed "white matter hypodensity in the left cerebral hemisphere [which] m[ight] be related to chronic microvascular changes, however taking into account the asymmetry, a subacute infarct c[ould not] be ruled out." Id. at 273. A follow-up MRI was thought to be consistent with her previous MRI "that showed ADEM;" there was no suspicion for progression of disease. Id. at 280. Lab and imaging testing revealed evidence of chronic liver disease. Id. at 256.

Petitioner reported that she had previous heavy alcohol use. Pet. Ex. 14 at 256. Her son indicated she was a "daily drinker historically, recently sober." Id. at 231-32. Her sister, who was also with her at the hospital, stated Petitioner "ha[d] [a] heavy alcohol history, but quit approx[itmately] [six] [weeks] ago." Id. During consultation with hematology, her alcohol use history was noted as follows: "[Petitioner] has a history of alcohol abuse that started following the diagnosis of ADEM and had been consuming the equivalent of [seven] shots of vodka per

[26] Xanax is the trademark name of alprazolam, "a short-acting benzodiazepine used as an antianxiety agent." Alprazolam, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=1937 (last visited Jan. 16, 2025).

[27] Hepatic encephalopathy is "a condition usually seen secondary to advanced disease of the liver . . . . It is marked by disturbances of consciousness that may progress to deep coma (hepatic coma), psychiatric changes of varying degree, flapping tremor," and bad breath. Hepatic Encephalopathy, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=73079 (last visited Jan. 16, 2025).

day, until [six] weeks ago when she stopped drinking alcohol." Id. at 392. The impression was hepatic encephalopathy, likely EtOH (ethanol) liver disease, hypothyroidism, and ADEM. Id. at 256. Her acute changes were felt to be due to the hepatic encephalopathy. Id. at 263, 274. Her ADEM was stable. Id. at 256, 299. She was treated in the hospital with lactulose and thiamine and improved to the point she was released on November 22, 2019, with instructions to follow up with her physicians. Id. at 256-63.

On January 15, 2020, Petitioner followed up with Dr. Lovera. Pet. Ex. 13 at 4-7. Her active problem list included ADEM. Id. at 4. The gabapentin was reportedly helping with her pain. Id. Upon examination, her condition was unchanged. Id. The impression included cirrhosis of the liver, encephalitis, myelitis, encephalomyelitis following immunization, and significant cognitive deficits. Id. The plan included continued physical and occupational therapy and continued gabapentin. Id. She was also encouraged to follow up with psychiatry and gastrointestinal specialists. Id.

On January 22, 2020, Petitioner attended a follow-up appointment at University Medical Center for presumed alcoholic cirrhosis, ADEM, and Hashimoto's thyroiditis. Pet. Ex. 14 at 72-81. She complained of leg swelling, muscle spasms, insomnia, and depression. Id. at 78. She denied numbness, paresthesias, and burning sensations in her feet. Id. Her alcohol use history was recorded as "former heavy drinker, quit 10/2019." Id. at 79. The impression included ADEM secondary to MMR vaccine. Id. She was assessed as stable and was advised to maintain close follow-up with neurology for her chronic conditions and continue her medications. Id. at 80.

On January 28, 2020, Petitioner was seen in the hepatology clinic for decompensated cirrhosis and anemia. Pet. Ex. 14 at 36. She was scheduled to see the liver transplant team. Id. at 38-42. Petitioner continued to be treated for end stage liver disease throughout early 2020 and on July 5, 2020, she underwent a liver transplant. See generally Pet. Ex. 16.

Petitioner had follow-up visits with neurologist Dr. Lovera on October 20, 2021 and September 28, 2022. Pet. Ex. 52 at 14. In 2021, she reported feeling "ok overall." Id. She was neither improving nor getting worse. Id. She had decreased sensation of her lower right leg and continued to have problems with balance, dizziness, and memory. Id. She was one year post-liver transplant and had experienced transient worsening of liver function that eventually normalized. Id. On September 28, 2022, she reported no new problems, and that she was doing better post-liver transplant. Id.

On June 27, 2023, Petitioner had a follow-up appointment with Dr. Lovera. Pet. Ex. 52 at 14. She reported continued issues with balance and dizziness and with memory retrieval and recent memories but was able to walk as far as she wanted on level ground. Id. Lyrica[28] was helping her neuropathic pain. Id. Dr. Lovera noted that a January 19, 2023 brain MRI revealed

[28] Lyrica is the trademark name for pregabalin an anticonvulsant used in the treatment of neuropathic pain. Pregabalin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=40751 (last visited Jan. 16, 2025).

no new lesions as compared to her 2019 scan. Id. at 15. Upon examination, she had full strength in both legs but decreased sensation to touch. Id. at 17. Dr. Lovera referred her to PT. Id. at 12.

Between August 9, 2023 and September 23, 2023, Petitioner attended eight PT sessions. Pet. Ex. 52 at 1-10. An initial evaluation revealed gait abnormalities, generalized weakness, poor balance and stability, and reports of pain and limitation with functional activities. Id. at 10.

At each session thereafter, her therapist recorded steady improvement. See, e.g., Pet. Ex. 14 at 2-4.

D. Petitioner's Affidavits and Testimony

Petitioner executed an affidavit in 2020[29] and a second affidavit in 2021. Pet. Exs. 15, 31. Petitioner also testified at the entitlement hearing. Tr. 6-27.

Petitioner testified that prior to receiving the MMR and varicella vaccines, she was very healthy. Tr. 9. Petitioner, a registered nurse ("RN"), was working about 50 hours a week doing clinical documentation integrity. Id. Her job involved reviewing charts along with physicians' documentation to ensure that the hospital was reimbursed appropriately. Id.; Pet. Ex. 31 at ¶ 5. Prior to working in clinical documentation, Petitioner spent ten years working as a staff nurse, and then charge nurse, at East Jefferson Hospital on "42-bed med-surg unit." Tr. 8; Pet. Ex. 15 at ¶ 2.

In 2018, Petitioner accepted a position at UCLA Santa Monica to teach physicians and staff about clinical documentation integrity. Pet. Ex. 15 at ¶ 4. Petitioner was required to receive the MMR and varicella vaccinations for her new position. Id. at ¶ 4; Tr. 10

On October 1, 2018, Petitioner received MMR and varicella vaccines at Walgreens. Pet. Ex. 15 at ¶ 4; Tr. 10.

On or around October 13, 2018, Petitioner flew to California to begin the new nursing position. Pet. Ex. 15 at ¶ 4. She had pain in her feet as she walked through the airport. Id. Her feet continued to feel numb, swollen, and have pins and needles type pain, and Petitioner felt "very tired" and "worn out." Id. at ¶ 5; Tr. 10. She experienced double vision. Pet. Ex. 15 at ¶ 8. She felt like she had a low-grade fever. Id. She felt "generally unwell" the entire week; however, the symptoms she experienced "seemed mild at the time." Id. at ¶ 6. Petitioner continued to experience "low-grade fever, ascending pins and needles, [and] numbness" and she developed "severe loss of appetite" as well as "weight loss, severe fatigue, joint pain, brain fogginess, [and] double vision." Id. at ¶¶ 9, 11.

At this point in time, Petitioner did not have health insurance as her COBRA insurance was "extremely expensive" and Petitioner felt "extremely healthy" and had rarely utilized her insurance. Pet. Ex. 15 at ¶ 7. Since Petitioner was changing jobs, she felt she could wait 90 days for new insurance. Id.; Tr. 11. Petitioner testified that she did not initially see a doctor because

[29] Petitioner's affidavit is undated but was filed on July 25, 2020. Pet. Ex. 15 at 5.

she did not have health insurance. Tr. 11. Her increasing symptoms affected her ability to work, and ultimately she stopped working on December 31, 2018. Tr. 12. She returned home and begin seeking treatment in January 2019. Id. Petitioner recounted her visits with different physicians in 2019, until she saw Dr. Lovera. Tr. 15. When she saw Dr. Lovera, she was unable to drive and required assistance with all her activities of daily living. Id. She testified that was diagnosed with ADEM on May 1, 2019. Id.

Petitioner testified that due to difficulty sleeping and the intensity of her pain, she began self-medicating with alcohol. Tr. 18. She self-medicated with alcohol for "about a year" and later received a liver transplant. Id.

Petitioner explained that at the time of the 2018 vaccinations she was not diagnosed or being treated for high blood pressure. Tr. 23. She testified that had taken medication for high blood pressure "much earlier, [] when [she] was pregnant." Id.

In her November 28, 2021 affidavit, Petitioner explained that even on a "good day post-ADEM," she felt fatigued, her world felt much smaller, and she felt isolated from her family. Pet. Ex. 31 at ¶¶ 8-10. On a "bad day post-ADEM," she had dizziness, nausea, pain and numbness, and required assistance getting up, getting dressed, and getting into vehicles. Id. at ¶¶ 12-17.

Petitioner testified that, as of the May 1, 2024, the date of the entitlement hearing, she continues to experience discomfort and numbness in her feet, especially on the left side, and in her left arm. Tr. 25-26. She continues to experience brain fog and has "trouble finding [] words a lot of the times." Tr. 26. She has trouble with her memory, her balance, and with dizziness. Id. She also has difficulty with recall. Tr. 26-27. She continues to suffer from hypothyroidism for which she takes medication. Tr. 27.

E. Shannon Lobell's Affidavit

Petitioner's sister, Ms. Shannon Lobell, executed an affidavit on November 30, 2021. Pet. Ex. 30 at ¶ 1.

Ms. Lobell averred Petitioner became ill in October 2018 after she received the MMR vaccine for work. Pet. Ex. 30 at ¶ 1. Ms. Lobell explained that before she got sick, Petitioner worked long hours and used to work 16-hour shifts three days a week as a nurse so that she could care of both their children on the other four days of the week. Id. at ¶ 2. Later in her career, Petitioner would start work at four in the morning so that she could care for her children after work. Id. at ¶ 6. Additionally, Petitioner helped care for their elderly parents. Id. at ¶ 5. Ms. Lobell "frequently wondered where [Petitioner's] energy came from." Id. at ¶ 6.

In October of 2018, Petitioner complained to Ms. Lobell of a "strange constellation of symptoms." Pet. Ex. 30 at ¶ 7. Petitioner had "pain, numbness, and tingling in her legs and feet" and "a brain fog condition as well as low grade fevers." Id. Ms. Lobell accompanied Petitioner to doctors appointments with a rheumatologist, endocrinologist, and neurologist. Id. at ¶ 8. Ms. Lobell explained that Petitioner's balance was very bad; she was frequently falling and in "a lot

of pain with every step." Id. at ¶ 9. When Ms. Lobell brought Petitioner for an MRI appointment, she had to support most of Petitioner's body weight walking into the facility because Petitioner was "so weak and her balance was so poor." Id. Ms. Lobell was with Petitioner when she was diagnosed with ADEM. Id. at ¶ 8. She also accompanied Petitioner to a cognitive evaluation where the neurologist told Petitioner she would be unable to return to work as a nurse. Id. at ¶ 10.

After Petitioner began PT, Ms. Lobell would accompany Petitioner on walks in her neighborhood on days that Petitioner did not have PT. Pet. Ex. 30 at ¶ 12. Ms. Lobell explained that Petitioner's balance was not steady enough for her to walk alone. Id. She further explained that "every step was extremely painful for [Petitioner]" and "[m]any days we only walked the distance of two or three suburban homes." Id.

Ms. Lobell explained that while Petitioner is stable in her condition, she "has not improved anymore in a long time." Pet. Ex. 30 at ¶ 13. As of November 30, 2021, Petitioner is unable to work and cannot walk or drive long distances. Id. Petitioner continues to suffer from "brain fog." Id. Ms. Lobell assists Petitioner with grocery shopping, caring for her home, and with paying her bills in a timely manner. Id. at ¶ 14.

F. Expert Reports and Testimony[30]

1. Petitioner's Expert, Dr. Carlos Tornatore[31]

a. Background and Qualifications

Dr. Tornatore is a board-certified neurologist. Pet. Ex. 17 at 2; Pet. Ex. 18 at 1. He received his M.D. from Georgetown University School of Medicine where he subsequently completed a neurology residency at Georgetown University Hospital. Pet. Ex. 17 at 2. He completed a post-doctoral fellowship at the National Institutes of Neurologic Disorders and Stroke at the National Institutes of Health. Id. at 2. Dr. Tornatore then joined the faculty at Georgetown. Id. He is currently a Professor and Chairman of the Department of Neurology at Georgetown University Medical Center; Chairman and Neurologist-in-Chief of the Department of Neurology at Medstar Georgetown University Hospital; and the Director of the MS Center at Georgetown. Id.; Pet. Ex. 18 at 3-4. In his practice, he sees and treats patients with ADEM, MS, and other autoimmune disorders as well as patients with inflammatory diseases of the peripheral nervous system. Pet. Ex. 17 at 2; Tr. 31-32. He also serves as an ad hoc reviewer for five medical journals and has authored or co-authored publications on neurology, neuroimmunology, clinical immunology, and neurovirology over the course of his career. Pet. Ex. 18 at 7-14; Tr. 30.

[30] Although the undersigned has reviewed all of the expert reports and expert testimony, for the sake of brevity this Ruling does not include every detail of the experts' opinions. Instead, the undersigned focuses on the experts' material opinions, as they relate to the relevant issues.

[31] Dr. Tornatore submitted two expert reports and testified at the hearing. Pet. Exs. 17, 43; Tr. 3.

b. Opinion

Dr. Tornatore opined, to a reasonable degree of medical certainty, that the MMR and varicella vaccines caused Petitioner to develop ADEM. Tr. 37, 46-47; Pet. Ex. 17 at 15.

i. Diagnosis

Dr. Tornatore opined that Petitioner's appropriate diagnosis is ADEM. Tr. 37; Pet. Ex. 17 at 13. Dr. Tornatore based his diagnosis opinion on the opinions of Petitioner's treating neurologists as well as his own review of Petitioner's imaging studies, test results, and medical records. Pet. Ex. 17 at 13; Tr. 37. He noted that Petitioner's treating physicians diagnosed her with ADEM. Tr. 37.

Dr. Tornatore explained that ADEM may cause a range of neurological symptoms including cognitive issues, motor issues, weakness, sensory issues such as numbness, tingling and pain, tremor, gait instability, and vision loss. Tr. 39. Petitioner exhibited common neurological symptoms of ADEM including ascending numbness of the feet, fatigue, brain fog, gait instability, and persistent changes in the arms and legs. Id. In his review of the medical records, Dr. Tornatore noted both subjective and objective symptoms indicative of ADEM including sensory changes in the legs and trunk, fatigue, neuropathic pain, weakness and sensory changes in the extremities, as well as cognitive, gait, and sensory abnormalities which began in October and/or November of 2018. Pet. Ex. 43 at 1-2. Petitioner's neurological symptoms were persistent; however, Dr. Tornatore explained that persistent symptoms are not "out of the ordinary" in ADEM. Tr. 40.

After discussing Petitioner's clinical course, and how it was consistent with ADEM, Dr. Tornatore explained that Petitioner's diagnostic testing also supported a diagnosis of ADEM. Tr. 40. Specifically, Dr. Tornatore opined that Petitioner's MRI imaging, CSF results, EMG, and blood work were all consistent with an ADEM diagnosis. Pet. Ex. 17 at 13, Pet. Ex. 42 at 1-2.

Reviewing Petitioner's April 25, 2019 MRI, Dr. Tornatore explained that "the imaging characteristics of [Petitioner's] lesions are confluence, asymmetry and very consistent with resolved ADEM." Pet. Ex. 43 at 5. The MRI showed widespread white matter changes, more on the left side than the right, and including in the left thalamus. Tr. 40; Pet. Ex. 43 at 6-7; see also Pet. Ex. 6 at 33-34. Dr. Tornatore testified that the asymmetric pattern, location of the white matter changes, and the involvement of the thalamus, is "very typical of ADEM." Tr. 40.

Further, Dr. Tornatore noted that Petitioner's treating physician, Dr. Lovera, reviewed Petitioner's MRI studies and thought they were consistent with ADEM. Tr. 185.

Dr. Tornatore disagreed with Respondent's expert, Dr. Leist, that Petitioner's MRIs could be due to alcohol/metabolic disease, hypertension, or thyroid disease. Tr. 101-02. He explained that in those conditions, the MRI would be expected to show diffuse symmetrical changes. Id. Instead, Petitioner's MRI had focal asymmetrical changes consistent with a demyelinating condition as noted by the reading radiologist. Id. Further, the changes seen on Petitioner's MRI are not characteristic for those caused by alcohol. Tr. 105. Moreover, the cognitive effects that

Petitioner has are related to ADEM and not alcohol. Tr. 107. Specifically, Dr. Tornatore explained that Petitioner's MRI shows ADEM lesions in the left hemisphere where speech is controlled. Tr. 107-08. Petitioner has issues with speech, and he noted that her MRI is consistent with this clinical manifestations of her ADEM. Tr. 108.

He also disagreed with Dr. Leist that Petitioner's MRI was inconsistent with ADEM due to the absence of infratentorial lesions.[32] Tr. 184. While Dr. Leist opined that the lack of infratentorial lesions pointed away from ADEM as a diagnosis, Dr. Tornatore cited Schwarz et al.[33] for the proposition that 35% of patients do not have infratentorial lesions. Id. (citing Resp. Ex. I, Tab 8 at 3-4).

Dr. Tornatore also disagreed with Dr. Leist that in ADEM, MRIs improve over time. Tr. 184-85. He opined that up to 15-20% of patients will have persistent symptoms and MRI findings, like Petitioner. Tr. 185. He relied on Noorbakhsh et al. who explained that while "50% to 70% of patients completely recover[] without neurologic sequelae," common residual effects include "focal deficits" ranging from "mild ataxia to hemiparesis." Pet. Ex. 20 at 16; Tr. 185. The authors explained that the degree of impairment is believed to be due to the "extent of neuronal and axonal damage" suffered by the patient. Pet. Ex. 20 at 16. Therefore, Petitioner's persistent symptoms, and the fact that her MRI results remained stable and did not improve over time, did not change Dr. Tornatore's opinions. Tr. 184-85. Dr. Tornatore also cited a paper by Li et al., which reported the outcomes of 437 adult ADEM cases (11 retrospective studies and 1 prospective study). Pet. Ex. 55 at 3. Of these, 7.8% of the patients died, and almost half suffered residual effects over the follow-up period of approximately three to six years. Id. at 4.

Regarding the fact that Petitioner did not suffer from encephalopathy associated with her ADEM, Dr. Tornatore explained that a minority of patients, approximately 20%, have ADEM without encephalopathy. Tr. 96-97, 186. In support, he again cited Li et al., which reported the frequency of encephalopathy in adults with ADEM was 43% and concluded "the absence of encephalopathy should not discourage" an ADEM diagnosis. Tr. 186 (citing Pet. Ex. 55 at 6).

Next, Dr. Tornatore explained that Petitioner's April 25, 2019 CSF did not show inflammation, which was consistent with ADEM. Tr. 41; Pet. Ex. 17 at 6. Petitioner's January 13, 2019 blood work was also consistent with "systemic inflammation with multiorgan

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[32] Infratentorial means "beneath the tentorium of the cerebellum." Subtentorial, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=47826 (last visited Jan. 24, 2025). The tentorium of the cerebellum is the "dura mater that supports occipital lobes and covers the superior surface of the cerebellum. Its anterior concave border is free and bounds the tentorial notch; its posterior and lateral convex border is attached to the skull and encloses the transverse sinus posteriorly and the superior petrosal sinus anteriorly." Tentorium Cerebel'li, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=112364 (last visited Jan. 24, 2025).

[33] S. Schwarz et al., Acute Disseminated Encephalomyelitis: A Follow-Up Study of 40 Adult Patients, 56 Neurology 1313 (2001).

involvement" including the liver and thyroid. Pet. Ex. 17 at 3. Dr. Tornatore testified that Petitioner's blood work demonstrated peripheral inflammation also consistent with ADEM. Tr. 43.

Additionally, Petitioner's April 2019 EMG showed significant axonal and demyelinating neuropathy. Tr. 60; see Pet. Ex. 6 at 17. Dr. Tornatore explained that the EMG was "hard evidence that there is involvement of the nervous system" and the peripheral nerves consistent with ADEM. Tr. 68.

Finally, addressing Petitioner's delay in seeking treatment, Dr. Tornatore explained that it is not unusual for patients to put off medical treatment when they have concerns about insurance. Tr. 46. He further explained that not all ADEM patients are so acutely ill that they require hospitalization. Tr. 95. He concluded that nothing in Petitioner's clinical presentation is inconsistent with her diagnosis of ADEM. Tr. 190.

ii. Althen Prong One

Dr. Tornatore opined ADEM is an acute autoimmune inflammatory event of the CNS which can be triggered by a variety of antigens, including vaccinations. Pet. Ex. 17 at 13. Dr. Tornatore further opined that molecular mimicry is the proposed biological mechanism of Petitioner's vaccine-induced ADEM. Id. at 14. He explained that ADEM has long been recognized as a rare sequela of vaccination. Id.at 13; Tr. 50-52. Dr. Tornatore provided medical literature in support of this proposition, citing to articles by Tenembaum et al.[34] and Noorbakhsh et al. Tr. 50-52 (citing Pet. Exs. 20-21).

In Tenembaum et al., the authors reported a "clear infectious event or vaccination preceded the onset of [ADEM] in 74% of patients." Pet. Ex. 21 at 2. They noted that ADEM "often follows a viral illness or vaccination." Id. at 1. Immunization was the precedent event to ADEM in 10 of 84 (12%) patients studied. Id. at 2 tbl.1. Seven of the 10 patients had received a measles vaccine. Id.

Noorbakhsh et al. also recognized that ADEM typically follows "a viral infection or immunization." Pet. Ex. 20 at 1. They referred to ADEM as a "post-vaccinal encephalomyelitis." Id. ADEM has been associated with the measle vaccination, as well as other vaccines, however, the authors noted that cases following the live attenuated measles vaccine have not been well documented. Id. at 6, 8.

Dr. Tornatore then posited that molecular mimicry explains the development of post-vaccinal ADEM. Pet. Ex. 17 at 13-14. Dr. Tornatore explained that

> [v]accinations, including the MMR and [varicella] vaccine[s,] are nothing more than a collection of antigens in the guise of attenuated viruses intended to trigger a protective immune response in the host. In rare events however, the immune

[34] Silvia Tenembaum et al., Acute Disseminated Encephalomyelitis: A Long-Term Follow-Up Study of 84 Pediatric Patients, 59 Neurology 1224 (2002).

> response to the vaccination results in humoral and cellular responses that target not only the vaccine antigens, but self-antigens which bear a resemblance to the vaccine antigens. When these self-antigens are targeted by this aberrant autoimmune response, the result is an inflammatory cascade which results in organ damage. In the case of the nervous system, the inflammatory cascade may affect any portion of the neuroaxis, resulting in a variety of symptoms.

Id. at 13. Dr. Tornatore cited to Noorbahksh et al. in support of molecular mimicry as the mechanism driving this inflammation and quoted the article extensively when he testified. Id. at 14; Tr. 53-55 (citing Pet. Ex. 20). The authors explained that "if self- and non-self-pathogen derived antigens share the same epitopes, presentation of the epitope to the immune system with concomitant activation of a primary innate immune-mediated inflammatory reaction might lead to activation of self-reactive lymphocytes, with subsequent infiltration of the target organ." Pet. Ex. 20 at 12.

Dr. Tornatore acknowledged that no target antigen has been identified for ADEM. Pet. Ex. 17 at 14. But he explained that, "[g]iven that there are thousands of potential antigens expressed in the nervous system, it is highly probable that sequence homology can be found between any vaccine antigen and brain antigens." Id.

iii. Althen Prong Two

Dr. Tornatore opined that there was a reasonable sequence of cause and effect between Petitioner's MMR and/or varicella vaccines and her ADEM. Pet. Ex. 17 at 15.

First, prior to vaccination, Petitioner had no documented neurological symptoms or cognitive issues. Tr. 58. After vaccination, around October 13, 2018, she noticed fatigue followed by ascending numbness of her feet, nausea, and appetite loss. Tr. 59. Dr. Tornatore explained that Petitioner's numbness indicated she had inflammation of the peripheral nerves as part of her ADEM illness, as well as other constitutional symptoms. Tr. 60. Blood work drawn in January 2019 showed elevated TSH, anemia (inflammation of the bone marrow), elevated ESR (another indicator of inflammation), and elevated alkaline phosphatase and bilirubin (indicating inflammation of the liver). Tr. 61-64. All these abnormalities indicated peripheral inflammation and inflammation of multiple organ systems. Tr. 64, 89.

In April 2019, Petitioner saw an endocrinologist, and she reported exhaustion, hair loss, brain fog, and neuropathy that occurred after vaccination. Tr. 66. Dr. Tornatore opined that all these symptoms "paint[] a straight line back . . . to the October time frame as the starting time." Id. Diagnostic testing was done, and the CSF, EMG, and MRI were all consistent with ADEM. Tr. 68.

He disagreed with Respondent's expert, Dr. Leist, that Petitioner's abnormal liver results in January 2019 indicated potential evidence of cirrhosis. Tr. 181. Dr. Tornatore agreed that Petitioner's lab results showed inflammation of the liver, but not cirrhosis or evidence of more

advanced liver disease. Id. He cited Hazeldine et al.,[35] an article relied on by Dr. Leist, which states that it "takes upwards of ten years of alcohol-related lever disease to progress from fatty liver through fibrosis, to cirrhosis, to acute cirrhosis and liver failure." Tr. 181-82 (quoting Resp. Ex. I, Tab 4 at 1). Further, he explained that the medical records prior to October 2018 do not suggest that Petitioner was counseled to stop drinking or told she was drinking too much. Tr. 182. Dr. Tornatore asserted that medical providers identify and counsel patients that are risk for liver disease. Id. Moreover, there are no indications that Petitioner had issues at work due to drinking. Tr. 182-83. Lastly, Dr. Tornatore explained that Petitioner's MRI was not consistent with a ten-year drinking history. Tr. 192.

Even if Petitioner did have a ten-year history of drinking, Dr. Tornatore testified that his opinions would not be any different. Tr. 191-92. Assuming her drinking was long standing and stable, he explained that something else happened. Tr. 191. Further, if there was a ten-year history of alcoholism, he would have expected to see "a lot more shrinkage of the brain," which Petitioner's MRI did not show. Tr. 192. Finally, he opined that alcohol does not cause white matter changes and asymmetric changes that were seen on Petitioner's MRI. Id.

Next, Dr. Tornatore disputed Dr. Leist's opinion that Petitioner's hypothyroidism must have existed prior to vaccination. Tr. 183. Dr. Tornatore testified that autoimmune hypothyroidism can begin acutely, as it did in Petitioner's case. Id. He cited to literature published by the American Thyroid Association which stated that "autoimmune hypothyroidism can begin suddenly." Id. (quoting Pet. Ex. 57 at 6).[36] While he agreed that in most people, autoimmune hypothyroidism occurs slowly over a course of years, he disagreed that it could not occur suddenly. Id.

Lastly, Dr. Tornatore testified that none of Petitioner's treating physicians attributed her ADEM diagnosis to alcohol or any cause other than her vaccinations. Tr. 112.

iv. Althen Prong Three

Dr. Tornatore opined that Petitioner's symptoms started within a month of her receipt of vaccinations. Pet. Ex. 17 at 15; see also Pet. Ex. 43 at 3-5. Her onset of symptoms was approximately two weeks[37] after she received her vaccinations on October 1, 2018. Tr. 74. Dr. Tornatore stated that this two-week onset period was medically appropriate based on his experience, the literature, and "the kinetics of immune response to vaccine or to any other foreign epitope." Id.

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[35] Simon Hazeldine et al., Alcoholic Liver Disease – The Extent of the Problem and What You Can Do About It, 15 Clinical Med. 179 (2015).

[36] Am. Thyroid Ass'n, Hypothyroidism: A Booklet for Patients and Their Families (2019).

[37] Petitioner testified that she had pain and a sensation of pins and needles in her feet on October 13, 2018, during her trip to California for work. Tr. 10.

In support of Petitioner's onset timeframe, Dr. Tornatore noted that Petitioner's medical history—elicited from Petitioner on January 7, 2019, April 4, 2019, April 11, 2019, and May 1, 2019, by four different treating physicians—all included new onset neurological symptoms that occurred within approximately one month of vaccination. Pet. Ex. 43 at 3-4 (citing Pet. Ex. 10 at 7-8, Pet. Ex. 8 at 6-7; Pet. Ex. 6 at 12-20, Pet. Ex. 7 at 8-13).

Additionally, Dr. Tornatore explained that, while taken six months after vaccination, the April 2019 MRI, in conjunction with Petitioner's medical history and EMG, was supportive of Petitioner's mid-October 2018 onset of symptoms. Tr. 75-76. Petitioner had no history of neurological symptoms prior to October 2018. Pet. Ex. 17 at 13. When the MRI was taken, the lesions were at least three weeks old (as none the of lesions were enhanced). Tr. 76. Moreover, the MRI shows "profound changes" consistent with a high "burden of disease." Id. Given that Petitioner was asymptomatic prior to October 2018, Dr. Tornatore concluded that the lesions could not have been present prior to October 2018, as "Petitioner would not have been able to function with a burden of disease that high." Tr. 77. Dr. Tornatore testified that while "it's never quite clear exactly when things start[]" in patients in inflammatory disease, it is clinically appropriate to use patient history to determine when lesions occur. Tr. 76-77. Based on Petitioner's history, and the results of her MRI, one can determine the trajectory of her illness. Tr. 77.

Dr. Tornatore explained that neurological symptoms of ADEM typically present two to 30 days after the preceding infection or immunization but may present up to 42 days post-vaccination. Pet. Ex. 17 at 15; Pet. Ex. 43 at 4. In support, he cited articles by Tenembaum et al., Noorbakhsh et al., and Rowhani-Rahbar et al.[38] Pet. Ex. 17 at 15; Pet. Ex. 43 at 4; Resp. Ex. I, Tab 9; Tr. 57. In Tenembaum et al., the authors followed 84 patients and found a mean onset for neurological symptoms of 12.2 days, with a range of two to 30 days. Pet. Ex. 21 at 2. Noorbakhsh et al. stated "ADEM typically appears with the abrupt onset of neurologic symptoms [two] to 30 days after the occurrence of a preceding infection or vaccination." Pet. Ex. 20 at 1. In Rowhani-Rahbar et al., the authors concluded that an interval of two to 42 days was "biologically plausible," for the onset of ADEM. Resp. Ex. I, Tab 9 at 4.

2. Respondent's Expert, Dr. Thomas Leist[39]

a. Background and Qualifications

Dr. Leist is a board-certified neurologist. Resp. Ex. A at 1. He received a Ph.D. in Biochemistry from the University of Zurich in Switzerland and an M.D. from the University of Miami in Florida. Resp. Ex. B at 1. Thereafter, he completed an internal medicine internship at the University of Miami and a neurology residency at Cornell Medical Center/Sloan Kettering Memorial Cancer Center in New York. Id. Dr. Leist is a neurology professor at Thomas

[38] Ali Rowhani-Rahbar et al., Biologically Plausible and Evidence-Based Risk Intervals in Immunization Safety Research, 31 Vaccine 271 (2012).

[39] Dr. Leist submitted two expert reports and testified at the hearing. Resp. Exs. A, I; Tr. 3.

Jefferson University, where he also directs the Division of Clinical Neuroimmunology. Id.; Resp. Ex. A at 1. Additionally, he holds multiple hospital and administrative appointments. Resp. Ex. B at 1. He is regularly involved in the care of patients with neuroimmunological conditions, including ADEM, MS, transverse myelitis, and immune disorders of the peripheral nervous system. Resp. Ex. A at 1. Dr. Leist has authored or co-authored various publications on immunology, neuroimmunology, and imaging. Id., Resp. Ex. B at 6-11.

b. Opinion

Dr. Leist opined, to a reasonable degree of medical certainty, that Petitioner did not suffer adverse effects from the MMR and/or varicella vaccines she received in October 2018. Resp. Ex. I at 6; Resp. Ex. A at 9.

i. Diagnosis

Dr. Leist agreed that Petitioner was diagnosed with ADEM by her treating physician. Tr. 172. However, he opined that Petitioner does not and did not suffer from ADEM; rather, he attributed Petitioner's clinical course to pre-existing alcoholic liver disease, cirrhosis, and uncontrolled hypothyroidism. Resp. Ex. A at 9; Resp. Ex. I at 1; Tr. 126. He opined that Petitioner's other medical conditions are known to be associated with cerebral white matter disease and her other neurological symptoms. Resp. Ex. I at 1; Resp. Ex. A at 7.

Starting with Petitioner's clinical course, Dr. Leist testified that it was not consistent with ADEM for several reasons. First, he noted that Petitioner was not hospitalized for her condition. Tr. 127. Dr. Leist explained that the acute neurological symptoms of ADEM include encephalopathy, oculomotor abnormalities, and motor symptom abnormalities, and these problems generally require medical encounters or hospitalization. Resp. Ex. I at 2; Tr. 127-28.

In support of this opinion, Dr. Leist cited several articles. An article from Schwarz et al. reported on a follow-up study of 40 adult patients with ADEM. Resp. Ex. I, Tab 8 at 1. During the acute phase of the illness, all patients in the study were hospitalized. Id. at 2. However, this appeared to reflect the methodology of the study which used hospital records for chart review, and the authors did not offer opinions about whether a patient who did not seek hospital treatment would somehow fall outside the "operational criteria" they used to confirm a diagnosis of ADEM. Id. The Schwarz et al. criteria for ADEM was based on clinical examination showing acute unexplained neurological symptoms, brain MRI with one or more demyelinating lesions, and lumbar puncture that excluded CNS infection, vasculitis, or any other autoimmune condition. Id. at 1-2. The Schwarz et al. criteria did not require hospitalization. Id. at 2.

Dr. Leist also cited Dale and Branson[40] for the premise that patients with ADEM usually present with encephalopathy, whereas Petitioner did not have encephalopathy. Resp. Ex. I, Tab 1 at 1. The purpose of the article by Dale and Branson was to compare ADEM with MS to assist

[40] R.C. Dale & J.A. Bronson, Acute Disseminated Encephalomyelitis or Multiple Sclerosis: Can the Initial Presentation Help in Establishing a Correct Diagnosis?, 90 Archives Disease Child. 636 (2005)

practitioners in distinguishing between the two conditions. Id. The authors stated that "[p]atients with ADEM are more likely to present with encephalopathy." Id. This statement, however, should be interpreted in the context of the stated goal of the paper—to differentiate between ADEM and MS. When read in this context, the authors were instructing that patients with ADEM are more likely to have encephalopathy than patients with MS. Regardless, they did not state that encephalopathy was required for a diagnosis of ADEM. See, e.g., id. at 3 fig.3 (noting the presence of encephalopathy in ADEM was a "trend[] only"). Encephalopathy is noted to occur in 45-75% of patients with ADEM as compared with only 13-15% of patients with MS. Id. at 2.

Moving to Petitioner's diagnostic work-up, another reason that Dr. Leist disagreed that Petitioner had ADEM was based on his interpretation of Petitioner's April 2019 MRI. Resp. Ex. I at 3-4. Dr. Leist opined that the MRI showed involvement of both sides of the brain. Tr. 152. While he agreed there was greater involvement on the left side, he noted there was also involvement on the right side of the brain. Id. Dr. Leist also believed the radiologist interpreted the MRI as showing greater involvement on the left side but not only involvement on the left side. Id. He compared Petitioner's April 2019 MRI to a reference image in Dale and Bronson. Tr. 156-57 (citing Resp. Ex. I, Tab 1 at 2fig.2); see also Resp. Ex. I, Tab 6, at 3 fig.1 (providing reference imaging for Hashimoto's encephalopathy);[41] Resp. Ex. I, Tab 10 (discussing hypertension and white matter lesions);[42] Resp. Ex. I, Tab 12 (same).[43] Dr. Leist opined that because Petitioner's MRI did not look like the reference in Dale and Branson, Petitioner did not have ADEM. Tr. 156-57. However, he did not disagree that Petitioner's MRI was interpreted by the reading radiologist to be concerning for demyelinating disease. Tr. 151.

Next, Dr. Leist asserted that most ADEM patients experience improvement in their MRI findings over time. Tr. 157. For support, Dr. Leist relied again on Schwarz et al., who found that of their 20 adult ADEM patients, six had complete resolution of brain lesions, 11 patients had partial resolution, and three patients had new lesions on their follow-up MRIs. Resp. Ex. I, Tab 8 at 3-4. Since Petitioner's MRIs following her April 2019 MRI remained stable and did not show improvement, Dr. Leist opined that Petitioner did not have ADEM. Tr. 157.

Lastly, as it relates to the April 2019 MRI, Dr. Leist opined that Petitioner's MRI showed no infratentorial lesions, whereas the majority of ADEM patients have infratentorial lesions. Tr. 158. He acknowledged, however, that not all ADEM patients will have infratentorial lesions. Id.

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[41] Akiko Matsunaga et al., Serial Brain MRI Changes Related to Autoimmune Pathophysiology in Hashimoto Encephalopathy with Anti-NAE Antibodies: A Case-Series Study, 406 J. Neurological Scis. 116453 (2019).

[42] Christina Sierra et al., Connecting Cerebral White Matter Lesions and Hypertensive Target Organ Damage, 2011 J. Aging Rsch. 438978 (2011).

[43] Karolina Agnieszka Wartolowska & Alastair John Steward Webb, Midlife Blood Pressure Is Associated with the Severity of White Matter Hyperintensities: Analysis of the UK Biobank Cohort Study, 42 Eur. Heart J. 750 (2021).

Of note, the Schwarz et al. article stated that, in ADEM patients, MRIs show "one or multiple supra- or infratentorial demyelinating lesions." Resp. Ex. I, Tab 8 at 2. Therefore, Schwarz et al. referenced both supratentorial and infratentorial lesions as characteristic of ADEM. Dale and Branson do not reference infratentorial or supratentorial lesions, and instead stated that ADEM "lesions tend to be in the deeper white matter with periventricular sparing." Resp. Ex. I, Tab 1 at 2.

Dr. Leist next discussed the fact that Petitioner's April 2019 EMG results demonstrated peripheral neuropathy. Tr. 153. He cited Kharabanda et al.[44] for the proposition that EMGs showing peripheral neuropathy are found in significant numbers of individuals with alcoholism. Id. (citing Resp. Ex. D at 1). The authors followed 33 patients diagnosed with liver cirrhosis (with 17 patients having alcohol-related cirrhosis) and found peripheral neuropathy in 21% of patients. Resp. Ex. D at 1. Accordingly, Dr. Leist opined that Petitioner's EMG was not indicative of ADEM, but instead was due to liver injury and alcohol use disorder. Tr. 153-54. He also noted that the EMG does not indicate when Petitioner's peripheral neuropathy began. Tr. 153. Finally, Dr. Leist opined that ADEM would more likely lead to nerve root disturbance rather than peripheral neuropathy. Tr. 154, 175.

Lastly, Dr. Leist asserted that because Petitioner did not recover from her illness, her course was not characteristic of ADEM. Tr. 154-55. He testified that Petitioner had a sharp two month decline in early January 2019 which continued until April or May 2019. Tr. 155. He opined this was inconsistent with ADEM which is a "self-limited disease." Id. Dr. Leist explained that Tenembaum et al. and Noorbakhsh et al. showed 89% of patients had complete recovery and 50-75% of patients had full recovery within one to six months of appearance of symptoms, respectively. Tr. 166 (citing Pet. Ex. 21 at 7; Pet. Ex. 20 at 16). Therefore, he opined that Petitioner's clinical course, in which she continued to lose weight past the six-month mark, is less consistent with ADEM and more consistent with an underlying condition such as liver disease. Id.

Regarding Petitioner's CSF results, Dr. Leist agreed that they were consistent with ADEM. Tr. 162.

Dr. Leist also testified that he had no reason to doubt the history that Petitioner reported to her medical providers, including that related to the onset of her symptoms. Tr. 178.

ii. Althen Prong One

Dr. Leist opined there is insufficient evidence to support a causal relationship between MMR and/or varicella vaccines and ADEM. Resp. Ex. A at 6; Tr. 131-32. Although he opined that Petitioner did not offer a reliable theory of vaccine causation (molecular mimicry), he agreed that ADEM is "thought to be a post-infectious process . . . where [] the immune response to the agent ultimately becomes cross-reactive." Tr. 168, 171. Dr. Leist also agreed that the rabies

[44] Parampreet S. Kharbanda et al., Peripheral Neuropathy in Liver Cirrhosis, 18 J Gastroenterology & Hepatology 922 (2003).

vaccine had been associated with cases of ADEM, and that other vaccines have noted to have a temporal association with ADEM. Tr. 172.

In support of his opinion regarding the lack of proof of vaccine causation relative to ADEM, Dr. Leist only cited to the 2012 Institute of Medicine ("IOM") Report that found "[t]he evidence is inadequate to accept or reject a causal relationship between MMR vaccine [and varicella vaccine] and ADEM." Resp. Ex. A at 6-7 (quoting Resp. Ex. G at 2, 4).[45] The IOM Report also noted that wild-type varicella zoster and MMR infections have been associated with a development of ADEM and that "[a]utoantibodies, T cells, and molecular mimicry may contribute to the symptoms of ADEM." Resp. Ex. G. at 2, 4.

Dr. Leist explained that the IOM reviewed the Tenembaum et al. article and found it only provided evidence of a temporal association between MMR vaccination and ADEM. Tr. 131-32; see also Resp. Ex. G at 3-4. He further testified that Dr. Tornatore's opinion on causation appeared to be primarily based on temporality. Resp. Ex. A at 7; Tr. 132.

Dr. Leist did not address other facets of Dr. Tornatore's theory of causation. Specifically, Dr. Leist did not refute the proposition that molecular mimicry has been identified as a causal mechanism of vaccine-induced ADEM.

iii. Althen Prong Two

Dr. Leist opined that Petitioner's clinical course does not suggest vaccine causation. Resp. Ex. A at 7. Instead, he asserted that Petitioner had alternative causes for her symptoms, including cirrhosis and hypothyroidism. Resp. Ex. A at 9; Resp. Ex. I at 1; Tr. 126. He also noted that she had hypertension, and that she took Sudafed "which has been associated with potential vascular events." Tr. 134. In addition to high blood pressure, Dr. Leist noted that she had a history of smoking, and she was obese. Tr. 135.

In support of his opinion that hypertension can cause "white matter changes in the brain," Dr. Leist cited a paper by Sierra et al. Tr. 137 (citing Resp. Ex. I, Tab 10). The authors stated that high blood pressure is a major risk factor for "ischemic and hemorrhagic stroke . . . [and] small vessel disease predisposing to lacunar infarction, white matter lesions, and cerebral microbleeds, which are frequently silent." Resp. Ex. I, Tab 10 at 1. Dr. Leist also cited an article by Wartolowska and Webb. Tr. 138. The authors noted that "white matter hyperintensities progress with age and hypertension." Resp. Ex. I, Tab 12 at 1.

Regarding blood work drawn in January 2019, when Petitioner saw Dr. Perdue, Dr. Leist opined that the elevated bilirubin and borderline albumin indicated "potential liver damage." Tr. 141-42. He testified that it "would have been prudent to look [] into a potential liver injury" in Petitioner at this time. Tr. 144-45. Further, Dr. Leist opined that he "would have at least

[45] Inst. of Med., Varicella Virus Vaccine, in Adverse Effects of Vaccines: Evidence and Causality (Kathleen Stratton et al. eds., 2012); Inst. of Med., Measles, Mumps, and Rubella Vaccine, in Adverse Effects of Vaccines: Evidence and Causality (Kathleen Stratton et al. eds., 2012).

expected that an internist probably would have picked up on this and would have done some additional workup." Tr. 147. However, he agreed that generally, to cause liver injury, there must be a "decade-long intake of alcohol," and that it does not "happen overnight." Tr. 149.

Next, Dr. Leist testified that Hashimoto's thyroiditis can cause white matter disease of the brain, and that this diagnosis was considered in Petitioner. Tr. 150-51. He submitted an article by Matsunaga et al. that discussed brain MRI findings secondary to Hashimoto's encephalopathy. See Resp. Ex. I, Tab 6. However, Petitioner was never diagnosed with Hashimoto's encephalopathy, so the relevance of this article is not clear. Further, Dr. Leist acknowledged that Petitioner's MRI findings were different than those noted in Matsunaga et al. paper. Tr. 151-52.

Dr. Leist also submitted a paper by Daviet et al.[46] which discussed the association between heavy alcohol consumption and the effects on the brain, including "brain atrophy, neuronal loss, and poorer white matter integrity." Resp. Ex. I, Tab 3 at 1. However, Dr. Leist did not show that these findings were present on Petitioner's April 2019 MRI. See Resp. Ex. I at 2-3; Tr. 151-52, 156-59. He also did not establish that any of Petitioner's treating physicians or the radiologist who interpreted her April 2019 MRI results attribute the abnormalities to alcohol use or to those effects caused by alcohol use.

After discussing Petitioner's MRI findings, Dr. Leist turned to her EMG findings, which he opined showed peripheral neuropathy that he asserted can be caused by alcoholism. Tr. 153. He opined that ADEM leads to "nerve root disturbance" instead of a peripheral neuropathy. Tr. 154.

In summary, Dr. Leist opined that Petitioner had Hashimoto's thyroiditis. Tr. 167. Relative to Petitioner's clinical course in 2016, he thought it was "possible" that her thyroiditis caused or contributed to her hypertension. Id. Then moving forward to 2019, he opined that she had liver disease which progressed to the point that it required a liver transplant. Id. He disagreed with Dr. Tornatore that Petitioner had liver or thyroid inflammation caused by her vaccination. Tr. 168.

iv. Althen Prong Three

Dr. Leist opined that Petitioner did not experience neurological symptoms of ADEM within a biologically plausible timeframe. Resp. Ex. I at 2. Dr. Leist reported the medical literature supported a time frame of between two to 42 days for the onset of symptoms. Id. (citing to Resp. Ex. I, Tab 9); see also Tr. 128. He testified that onset is generally within 30 days of the triggering event. Tr. 128. Here, however, he asserted that there is no way to verify Petitioner's onset since she did not seek treatment within the first 30 days of her symptoms. Id.

Rowhani-Rahbar et al. reported on a "systematic process to define biologically plausible and evidence-based risk interval estimates for . . . febrile seizures and [ADEM]." Resp. Ex. I,

[46] Remi Daviet et al., Associations Between Alcohol Consumption and Gray and White Matter Volumes in the UK Biobank, 13 Nature Commc'ns 1175 (2022).

Tab 9 at 1. The authors concluded that an interval of two to 42 days was "biologically plausible," but a shorter interval of five to 28 days was recommended for epidemiological assessments. Id. at 4.

Dr. Leist opined that if Petitioner experienced an acute neurological symptom of ADEM within the 42-day onset window, she would have sought medical care. Tr. 129; Resp. Ex. I at 2. He noted that Petitioner had medical encounters for administration of a TB test on October 6 and returned on October 8, 2018 for the TB test to be read, and there was no mention of vaccine side effects. Resp. Ex. I at 2. Petitioner then did not have another medical encounter until January 7, 2019. Id.

On cross-examination, however, Dr. Leist conceded that there is nothing in the medical record to contradict Petitioner's symptoms of pain in her feet started mid-October 2018. Tr. 178. He further testified that he did not have any reason to doubt that Petitioner's onset of symptoms began in mid-October 2018. Id.

III. LEGAL FRAMEWORK

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, a petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to

establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

B. Factual Issues

Petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records).

Medical records, specifically contemporaneous medical records, are presumed to be accurate and generally "warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013). The weight afforded to contemporaneous records is due to the fact that they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." Id. To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)), mot. for rev. den'd, 142 Fed. Cl. 247 (2019), vacated on other grounds & remanded, 809 F. App'x 843 (Fed Cir. 2020).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege she suffered a Table Injury, she must prove a vaccine actually caused her injury. To do so, Petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The special master must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's

favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

IV. ANALYSIS

A. Diagnosis

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since "each prong of the Althen test is decided relative to the injury[,]" determining facts relating to the claimed injury can be significant in a case where diagnosis is not clear. Id. Here, the parties dispute diagnosis, and so it is appropriate to first resolve that issue.

For the reasons discussed below, the undersigned finds that Petitioner's appropriate diagnosis is ADEM.

First, Petitioner's treating physicians opined that her MRI showed a demyelinating condition and diagnosed her with ADEM. Her first neurologist, Dr. Khurana, documented a differential diagnosis of "acute disseminated demyelination" and "demyelinating disease of CNS" and he recommended Petitioner see a neurologist with expertise in demyelinating diseases. Pet. Ex. 6 at 24. Dr. Khurana did not include in his list of differential diagnoses any of the conditions suggested by Dr. Leist, including alcoholic disease, thyroid disease, or hypertension.

The radiologist who interpreted Petitioner's initial MRI study, Dr. Silvestri, concluded that it showed demyelinating lesions. Pet. Ex. 11 at 6-7. Dr. Silvestri did not conclude that Petitioner's MRI was suggestive of alcoholism or any other condition.

Neurologist and neuroimmunolgist Dr. Lovera took a very thorough history and performed a detailed neurological examination. Petitioner had weakness of the lower extremities bilaterally with the reflexes in the lower extremities diminished relative to the upper extremities.

Her sensation was also reduced in both the upper and lower extremities but more so in the lower extremities. Her gait was slow, and she was unable to tandem walk. Dr. Lovera personally read the April 2019 brain MRI and noted it was consistent with ADEM. He concluded that Petitioner had ADEM. This conclusion was based on her history, the close relation to the vaccination, and the fact that she received an MMR vaccine, a live virus vaccine. Dr. Lovera also suspected that the lesions seen on Petitioner's MRI all occurred at the same time. He further noted that her CSF was consistent with ADEM. And he also suspected a component of peripheral nerve involvement due to Petitioner's decreased reflexes. Dr. Lovera's assessment included ADEM, neuropathic pain, hypothyroidism, hypertension, anemia, insomnia, cognitive change, and major depressive disorder. Pet. Ex. 7 at 13. Thus, he agreed that Petitioner had a thyroid disorder and hypertension, but he attributed her neurological symptoms to ADEM.

Even after Petitioner's later diagnosis of cirrhosis and liver transplant, ADEM remained a current diagnosis by her treating neurologist. See Pet. Ex. 13 at 4-7 (showing that on January 15, 2020, Petitioner's active problem list included ADEM); Pet. Ex. 38 at 5 (showing that in October 2021, ADEM remained on Petitioner's active problem list); Pet. Ex. 45 at 36 (showing that in September 2022, ADEM remained on Petitioner's active problem list); Pet. Ex. 53 at 6 (showing that in June 2023, ADEM remained on Petitioner's active problem list).

Here, the undersigned gives weight to the statements of Petitioner's treating physicians as they are "in the best position" to determine Petitioner's injury. See Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326; Cucuras, 993 F.2d at 1528 (noting contemporaneous medical records, "in general, warrant consideration as trustworthy evidence").

Next, the undersigned finds that Petitioner's MRIs and CSF support a diagnosis of ADEM. As described above, Petitioner's MRIs were consistent with ADEM, and the MRI findings were not explained by hypothyroidism, hypertension, or liver disease. Her April 2019 MRI was first read as "worrisome for demyelinating disease" with "widespread white matter gliotic signal change asymmetric and greater on the left involving both subcortical deep and basal ganglia especially the left thalamus." Pet. Ex. 11 at 6-7. Dr. Lovera later read the April 2019 MRI and found it supportive of ADEM rather than MS "because of the confluence of lesions and involvement of the thalamus." Pet. Ex. 7 at 13-14. Her subsequent MRIs had no new lesions consistent with ADEM, a monophasic disease. Further, the lesions identified in Petitioner's April 2019 MRI were not interpreted to be caused by alcoholic disease, hypertension, or thyroid disease, which would be expected to manifest as diffuse symmetrical changes rather than the asymmetrical changes present in Petitioner's April 2019 MRI.

Petitioner's April 2019 CSF testing was also consistent with an ADEM diagnosis, as conceded by Dr. Leist.

Lastly, Petitioner's expert, Dr. Tornatore, provided thorough and persuasive testimony regarding Petitioner's ADEM diagnosis. Dr. Leist's opinions about alternative causes were not as persuasive, especially given that none of Petitioner's treating physicians considered his alternative conditions as the cause of Petitioner's neurological symptoms.

In conclusion, the undersigned finds Petitioner has shown by preponderant evidence that her diagnosis is ADEM.

B. Causation

1. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 257 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

For the following reasons, the undersigned finds Petitioner has provided preponderant evidence of a sound and reliable theory by which the MMR and/or varicella vaccines can cause ADEM, and therefore, Petitioner has satisfied the first Althen prong.

First, ADEM is a disease known to be caused by vaccinations. Medical literature cited in this case by both parties supports the finding that vaccinations are associated with ADEM. See, e.g., Pet. Ex. 21 at 1-2 (noting ADEM typically follows a "viral infection or immunization"); Pet. Ex. 20 at 1 (same); Pet. Ex. 55 at 1 (noting ADEM "is commonly preceded by viral infections or vaccinations"); Resp. Ex. I, Tab 8 at 1 ("[ADEM] has been described as an uncommon, acute demyelinating disorder of the CNS, typically occurring after infections or vaccinations."); Resp. Ex. J at 4 (noting vaccinations, including MMR, have been implicated as a cause of ADEM).

Vaccine Program cases provide further support that vaccinations can cause ADEM. Special masters have found in favor of petitioners alleging ADEM following MMR and/or varicella vaccinations. See, e.g., Pasco ex rel. M.P. v. Sec'y of Health & Hum. Servs., No. 16-500V, 2022 WL 6616736 (Fed. Cl. Spec. Mstr. Sept. 23, 2022) (transverse myelitis and ADEM following MMR and varicella vaccinations); Eilan ex rel. A.E. v. Sec'y of Health & Hum. Servs., No. 15-381V, 2021 WL 1085925 (Fed. Cl. Spec. Mstr. Feb. 23, 2021) (ADEM following MMR and/or varicella vaccinations); Banks v. Sec'y of Health & Hum. Servs., No. 02-0738V, 2007 WL 2296047 (Fed. Cl. Spec. Mstr. July 20, 2007) (ADEM following the MMR vaccine).

Additionally, the undersigned and other special masters have routinely issued reasoned decisions granting entitlement to petitioners alleging ADEM following other vaccinations. See, e.g., Mullins ex rel. K.M. v. Sec'y of Health & Hum. Servs., No. 19-320V, 2024 WL 4045424 (Fed. Cl. Spec. Mstr. Aug. 8, 2024) (finding haemophilus influenzae type B ("Hib") and/or

Prevnar vaccines caused K.M.'s ADEM); Camerlin ex rel. Camerlin v. Sec'y of Health & Hum. Servs., No. 99-615V, 2003 WL 22853070 (Fed. Cl. Spec. Mstr. Oct. 29, 2003) (ADEM/transverse myelitis post-Hib vaccination); Kennedy v. Sec'y of Health & Hum. Servs., No. 09-474V, 2012 WL 1929801 (Fed. Cl. Spec. Mstr. May 8, 2012) (ADEM post-Tdap and/or meningococcal vaccinations); Lozano v. Sec'y of Health & Hum. Servs., No. 15-369V, 2017 WL 3811124 (Fed. Cl. Spec. Mstr. Aug. 4, 2017) (ADEM post-Tdap vaccination); Lerwick ex rel. Lerwick v. Sec'y of Health & Hum. Servs., No. 06-847V, 2011 WL 4537874 (Fed. Cl. Spec. Mstr. Sept. 8, 2011) (ADEM post-DTaP vaccination); Althen, 418 F.3d at 1282 (affirming lower court's finding of preponderant evidence that tetanus toxoid caused ADEM and optic neuritis); Brown v. Sec'y of Health & Hum. Servs., No. 09-426V, 2011 WL 5029865 (Fed. Cl. Spec. Mstr. Sept. 30, 2011) (ADEM post-influenza vaccine); Hawkins v. Sec'y of Health & Hum. Servs., No. 99-450V, 2009 WL 711931 (Fed. Cl. Spec. Mstr. Feb. 27, 2009) (ADEM following hepatitis B vaccination).

Although decisions of other special masters are not binding, the undersigned generally agrees with the reasoning of her colleagues in the above cited cases. See Boatmon, 941 F.3d at 1358; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

Next, the leading theory for how vaccines can cause ADEM is molecular mimicry. See Tr. 50-56 (Dr. Tornatore testifying that molecular mimicry is a biological mechanism for ADEM); see also Pet. Ex. 20 at 11-12; Resp. Ex. G at 2, 4. Literature filed in this case supports molecular mimicry as an accepted causal mechanism relative to ADEM. See Pet. Ex. 20 at 11 ("Molecular mimicry is one of the proposed mechanisms by which pathogens might lead to autoimmune responses."); see also Resp. Ex. G at 2, 4 (noting "[a]utoantibodies, T cells, and molecular mimicry may contribute to the symptoms of ADEM").

Further, case law also shows that the theory of molecular mimicry is an accepted theory for how vaccines can cause CNS demyelinating illnesses including ADEM. See, e.g., Palattao v. Sec'y of Health & Hum. Servs., No. 13-591V, 2019 WL 989380, at *35-37 (Fed. Cl. Spec. Mstr. Feb. 4, 2019) ("[M]any of the existing Program decisions in which [transverse myelitis] has been found to be caused by a vaccine rely on a mechanism [of] []molecular mimicry . . . ."); Caruso v. Sec'y of Health & Hum. Servs., No. 15-200V, 2017 WL 5381134, at *14, *14 n.19 (Fed. Cl. Spec. Mstr. Oct. 18, 2017) (finding a petitioner satisfied Althen prong one under a theory of molecular mimicry in an influenza/ADEM case); Reinhardt v. Sec'y of Health & Hum. Servs., No. 17-1257V, 2021 WL 1851491, at *16-18 (Fed. Cl. Spec. Mstr. Apr. 2, 2021) (determining a petitioner established Althen prong one in an influenza/bilateral optic neuritis case under the theory of molecular mimicry); Kennedy, 2012 WL 1929801, at *14 (finding Tdap and/or meningococcal vaccinations caused the petitioner's ADEM through molecular mimicry).

Specific to the MMR and varicella vaccines, Dr. Tornatore opines that the casual mechanism of molecular mimicry explains how these vaccines can cause ADEM. He provides a thorough and persuasive explanation of molecular mimicry. Dr. Tornatore could not identify a specific target antigen, but credibly explains that it is highly probable, given the vast amount of potential antigens in the nervous system, that sequence homology can be found for any vaccine and a brain antigen. Pet. Ex. 17 at 14. Moreover, the identification of a specific target antigen or

sequence homology is not required to establish Althen prong one. See, e.g., Hofer v. Sec'y of Health & Hum. Servs., No. 18-1752V, 2023 WL 4397810, at *20-21 (Fed. Cl. Spec. Mstr. June 12, 2023) (finding Petitioner satisfied Althen prong one without Dr. Tornatore identifying a specific antigen or homology); see also Knudsen, 35 F.3d at 549 (explaining that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program"). Although Dr. Tornatore has not provided a specific target antigen or sequence homology, the undersigned finds his explanation of molecular mimicry to be a sound and reliable theory to explain how vaccinations, including MMR and varicella, can cause ADEM.

Finally, Respondent's expert, Dr. Leist, did not effectively refute the mechanism of molecular mimicry as a sound and reliable theory.

For these reasons, the undersigned finds that Petitioner has proven by preponderant evidence a sound and reliable causal theory establishing that MMR and/or varicella vaccines can cause ADEM, satisfying Althen prong one.

2. Althen Prong Two

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. While the medical records and opinions of treating physicians must be considered, they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the "diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court").

A petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

For the following reasons, the undersigned finds preponderant evidence of a logical sequence of cause and effect establishing that the MMR and/or varicella vaccinations administered to Petitioner on October 1, 2018 caused her to develop ADEM.

First, as explained above, Petitioner was appropriately diagnosed with ADEM and Petitioner has proffered a sound and reliable mechanism of vaccine causation.

Second, Petitioner's treating neuroimmunologist attributed her condition to her MMR vaccination. In diagnosing Petitioner, Dr. Lovera explained that based "on the clinical history, the close relationship to the vaccination especially MMR which is a live virus," Petitioner had ADEM and he recommended Petitioner "apply for the vaccine compensation program . . . [as] there is a clear-cut time relation between the vaccination and the onset of symptoms." Pet. Ex. 7 at 13-14.

Treating physician statements are "favored" as treating physicians "are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280). Additionally, that a treating physician "relies in part on temporal proximity . . . to the administration of the vaccine is not disqualifying." Id.; see also Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1348 (Fed. Cir. 2010) (noting that the Special Master did not err in affording little weight to notations in which the treating physician simply indicated a temporal, but not causal, relationship between vaccine and injury). Here, Dr. Lovera did not only note a temporal relationship between the MMR vaccine, but he also considered the role of the live virus in the MMR vaccine as a factor in determining causation. The undersigned finds Dr. Lovera's statements on the relationship between MMR vaccine and Petitioner's ADEM persuasive and notes that they align with Petitioner's expert reports.

Additionally, following the April 2019 MRI and CSF testing, none of Petitioner's treating physicians attribute her ADEM symptoms to alternative causes such as alcoholism, hypertension, or hypothyroidism.

Dr. Leist asserts that Petitioner's hypothyroidism and liver disease were underlying conditions that existed at the time of Petitioner's vaccinations in October 2018. However, Petitioner's treating physicians did not attribute her neurological symptoms to her hypothyroidism. And her treatment for hypothyroidism did not resolve her neurological symptoms.

Petitioner's alcoholism did not manifest until after her October 2018 vaccinations. Petitioner testified that she began self-medicating with alcohol after her ADEM symptoms began. The medical records in this case are consistent with Petitioner's testimony. Petitioner's pre-vaccination medical records do not indicate alcohol abuse and her post-vaccination medical record make contemporaneous references to Petitioner using alcohol to self-medicate. For example, her medical history taken on November 18, 2019 notes "[Petitioner] has a history of alcohol abuse that started following the diagnosis of ADEM and [she] had been consuming the equivalent of [seven] shots of vodka per day, until [six] weeks ago when she stopped drinking alcohol." Pet. Ex. 14 at 392.

Accordingly, the undersigned finds that Dr. Leist's opinions do not carry sufficient weight to support alternative causation, and she finds that on the issue of alternative causes, the Petitioner's treating physicians and Dr. Tornatore's opinions are more persuasive.

In conclusion, the undersigned finds that Petitioner has proven by preponderant evidence a logical sequence of cause and effect establishing that the MMR and/or varicella vaccinations she received caused her to develop ADEM. Thus, Petitioner has satisfied the second Althen prong.

3. Althen Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That phrase has been defined as a "medically acceptable temporal relationship." Id. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen prong one). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1579, 1243 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542.

Petitioner received her vaccinations on October 1, 2018. Petitioner testified that her neurological symptoms began on or around October 13, 2018. Clinical histories taken on January 7, 2019, April 4, 2019, April 11, 2019, and May 1, 2019 place onset of Petitioner's symptoms between October 2018 and November 2018. Dr. Tornatore testified that onset was approximately two weeks after Petitioner received her vaccinations. He explained that Petitioner's clinical history and her April 2019 MRI and EMG were consistent with a mid-October 2018 onset of symptoms. Dr. Leist opined that it is impossible to determine when Petitioner's brain lesions occurred and opined that onset of ADEM within a 42-day window following the vaccine would have required a medical encounter. He also acknowledged, however, that he has no reason to doubt that Petitioner had an onset of pain about two weeks after her vaccinations.

Dr. Tornatore and Dr. Leist agreed that the medically acceptable timeframe was generally within 30 days of vaccinations. Further, Dr. Leist provided medical literature from Rowhani-Rahbar et al. supporting a time frame of two to 42 days for the onset of symptoms. Dr. Tornatore relied on medical literature from Rowhani-Rahbar et al., Tenembaum et al., and Noorbakhsh et al. to support an onset timeframe between two and 30 days.

The undersigned finds that Petitioner's clinical history and testimony are consistent with and support an onset in mid-October 2018, within one month of vaccination. Further, the undersigned finds that this onset is appropriate given the mechanism of molecular mimicry based on the testimony of the experts and their supportive medical literature.

Therefore, undersigned finds that Petitioner has met her burden of proof as to Althen prong three.

V. CONCLUSION

Based on the record, and for the reasons discussed above, the undersigned finds there is preponderant evidence that Petitioner's diagnosis is ADEM. Further, there is preponderant evidence to satisfy all three Althen prongs and to establish that Petitioner's MMR and/or varicella vaccinations caused her to develop ADEM. Thus, the undersigned finds that Petitioner is entitled to compensation.

On May 9, 2024, the undersigned issued an order directing the parties to begin working on damages. Order dated May 9, 2024 (ECF No. 116). On December 3, 2024, Petitioner filed the most recent joint status report addressing damages. Order dated Dec. 3, 2024 (ECF No. 136). The parties reported life care site visits have been set for December 2024 and January 2025 and the undersigned directed Petitioner to file a joint status report, providing an update on the life care plans, by February 3, 2025. Id. After this status report is filed, a status conference will be set to discuss resolution of damages.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master